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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,978

11/15/2006

Martin Pruschy

4-32911A

3436

1095

7590

04/04/2011

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

04/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,978	Applicant(s) PRUSCHY, MARTIN	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2010 has been entered.

Response to Arguments

2. The response filed 11/19/2010 has been entered.
3. Applicant's arguments filed 11/19/2010 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1, 4-5 and 11 are pending in this office action.

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6. It is noted that no arguments were sent in the reply 11/19/10. Since the final claim amendment was not entered, Examiner will now consider the remarks made on 9/21/10.

7. The rejections of claims 1, 4-5 and 11 under 35 U.S.C. 103(a) as being unpatentable over Danishefsky et al. (US Patent 6,242,469) in view of Bollag Exp. Opn. Invest. Drugs (1997) 6 (7):867-873 and Choy Critical reviews in Oncology/Hematology 37 (2001) 237- 247 is withdrawn as Choy now is withdrawn from the rejection and the response over Danishefsky et al. (US Patent 6,242,469) in view of Bollag Exp. Opn. Invest. Drugs (1997) 6 (7):867-873 is addressed below.

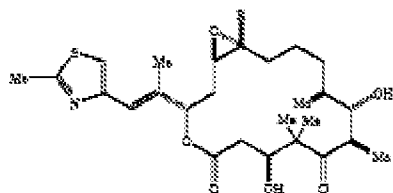
Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 4-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danishefsky et al. (US Patent 6,242,469) in view of Bollag Exp. Opn. Invest. Drugs (1997) 6 (7):867-873

Danishefsky et al. teach using pharmaceutical compositions of epothilones A and

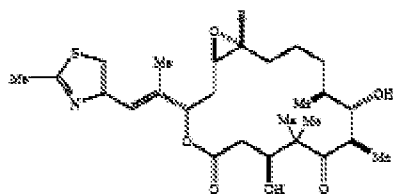


I Epothilone A R = H
II Epothilone B R = Me

B (i.e., wherein A in Applicant's chemical formula is O, R is methyl and Z is O would represent structure II of Danishefsky) for the treatment of solid tumor in a subject, wherein the solid tumor is breast cancer (as required by instant claims 1-3, 5 and 11; see abstract and col. 28 line 49-56). Reasonably treatment of breast cancer in a subject meets the limitation of treating a warm-blooded animal (as required by instant claim 4).

However Danishefsky et al. fail to teach the combination of epothilone b in combination with ionizing radiation.

Bollag teaches numerous solid tumors may be treated with the compounds of



I Epothilone A R = H
II Epothilone B R = Me

epothilones (i.e., , wherein A in Applicant's chemical formula is O, R is methyl and Z is O would represent structure II of Bollag) and further teaches that because of the similarity of function with a class of compounds (taxanes), epothilones possess similar or greater potencies than taxanes and should be further studied in combination with ionizing radiation, thus suggesting that these compounds can be combined with ionizing radiation.

It would have been obvious to one of ordinary skill in the art to expand the method of Danishefsky et al. to include the methods of Bollag because both Bollag teach or suggest the inclusion of ionizing radiation in the methods for treating solid tumors such as breast cancer.

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant method of treatment, given the teaching of the prior art methods of using Danishefsky et al. and Bollag individually for treating solid tumors, it would have been obvious to use both compounds for the treatment of solid tumors because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as therapeutic agents.

Applicant argues that 'The rejection appears to be based at least in part on the Examiner's contention that taxanes are similar in structure to epothilones. Applicant believes that this is incorrect and invites the Examiner to explain the basis for this position.

Applicant has provided two journal articles, Hofstetter et al and Bley et al, which demonstrate a supra additive effect when ionizing radiation and patupilone are combined. Applicant believes that the Examiner takes the position that the data is not

commensurate in scope with the claims and indicates that claims should include limits relating to dosage concentrations.

In response contrary to Applicant's assertion Applicant's arguments are found not persuasive for the following reasons:

With regards to the argument that the Examiner thinks or is under the contention that taxanes are similar in structure to epothilones found not persuasive because Examiner only stated the similarity in function as clearly supported by Bollag. Bollag specifically teaches epothilones are structurally distinct from taxanes but possesses similar tubulin polymerizing and cell biology effects (see abstract).

Next Applicant provision of journal articles with regards to the claims are not persuasive because according to "B. Hofstetter et al, Clinical Cancer Research, Vol. 11, 1588-1596 (2005)" and "Bley et al, Clinical cancer Research, Vol. 15(4), 1335-1342 (2009)" the additive result achieved were only observed with specific dosage concentrations, and alternatively the claims are very broad with no recited dosage amounts (see pages 1590-91 Fig's 1 and 2 of the result section of the Hofstetter and page 1338 of Bley).

Applicant should note that in Ex parte Gelles 22 USPQ 2d 1318 (at 1319): held that "[t]he evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter." Also in order to show unexpected result's three major points that should be considered: the unexpected result must truly be unexpected, it

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must be commensurate in scope (show a trend representing the scope), and lastly a direct comparison with the closest prior art of record should be provided.

It should be noted that Choy is withdrawn from the rejection.

After careful consideration Applicant's argument is found not persuasive for the reasons given.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
3/21/10

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/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628